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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/692,979	10/24/2003	William R. Campbell	PIED1110-1	1729
7590 STACY L. TAYLOR DLA PIPER US LLP Suite 1100 4365 Executive Drive San Diego, CA 92121-2133				
EXAMINER				
LEVY, NEIL S				
ART UNIT		PAPER NUMBER		
1615				
MAIL DATE		DELIVERY MODE		
08/31/2010		PAPER		

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

### Office Action Summary

**Application No.**

10/692,979

**Applicant(s)**

CAMPBELL ET AL.

**Examiner**

NEIL LEVY

**Art Unit**

1615

**Period for Reply** -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 05 August 2010.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-4, 12-16 and 32 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-4, 12-16 & 32 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/GS/US)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

### DETAILED ACTION

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

***Claim Rejections under - 35 USC § 112 are withdrawn, in view of amendments***

Claim 12-15 stand rejected under 35 U.S.C. 103(a) as obvious over SINGER et al 4147800

Almost 100% lice are killed within 24 hours (column 3, lines 22-38) by applying isopropanol and 50% isopropyl (IPM) myristate (1:1 to 1-column 2, lines 60-63) or less (column 4, top; column 3, lines 32-35). IPM above, at 70%, with polysorbate and water carrier, killed 100% lice (column 4, lines 21-32). Table I shows 100% kill with 100% IPM. Examples are with human lice, obviously inclusive of all species. Note alcohol at 25% killed no lice (Table II); 40% killed only 7% (column 3, bottom).

Curve 2 is only IPM (COL. 4, LINE 23-26) & POLYSORBATE @ 70%, WITH 15% DEATH IN A 2 MINUTE TEST thus meeting the instant claims which now require 0 % kill ("up to " is inclusive of 0).

NO OTHER AGENTS are needed, only IPM. As to the retention, examples show shampoos, lotions. Only shampoos would have a short time of retention, but lotions would be applied as is known in the art, without intentional removal; thus, retention of hours.

Claim 1-4, 32 stand rejected under 35 U.S.C. 103(a) as being unpatentable over SINGER

See above; Table I shows IPM alone kills 100% of lice, obvious to use prevent alcohol irritation (column 3, top) if subject is sensitive.

It would have been obvious to a person of ordinary skill in the art at the time the invention was made desiring to utilize pest control means, to use any of art recognized means, as of the ectoparasitidal, pediculicide compositions to control lice, modified as desired to decrease toxicity to patients.

All the critical elements of the instant are disclosed. The amounts and proportions of each ingredient are result effective parameters chosen to obtain the desired effects. It would be obvious to vary the form of the composition to optimize the effect desired, to optimize reduction of toxicity, cost minimization, enhanced, and prolonged, or synergistic effects.

Applicant has not provided any objective evidence of criticality, nonobvious or unexpected results that the administration of the particular ingredients' or concentrations provides any greater or different level of prior art expectation as claimed, and the use of ingredient for the functionality for which they are known to be used is not basis for patentability.

Claims 12-16, 32 stand rejected under 35 U.S.C. 103(a) as being unpatentable over SINGER et al 4147800 in view of REID et al 5972987 and further in view of Von Bittera et al 4544547.

SINGER (above) kills lice, but does not mention combing.

REID shows application of pediculicide and dye (column 4, lines 6-11) permit removal with combs (column 4, lines 50-56) from human or animal (lines 63-66) particularly head lice (column 5, lines 44-48). Example 1 shows use of silicone and IPM.

It would have been obvious to a person of ordinary skill in the art at the time the invention was made desiring to utilize pest control means, to use any of art recognized means, as of the pediculicide compositions of SINGER to control lice, modified as desired to decrease toxicity to patients. Motivation to combine springs from the IPM synergy of SINGER, with further removal of lice and nits facilitated by dye and comb of REID.

Von Bittera shows the application of IPM (example 2) in the control of ectoparasites of dogs & cats, including dog flea, dog louse, & ticks (col. 12, lines 23-40).

All the critical elements of the instant are disclosed. The amounts and proportions of each ingredient are result effective parameters chosen to obtain the desired effects. It would be obvious to vary the form of the composition to optimize the effect desired, to optimize reduction of toxicity, cost minimization, enhanced, and prolonged, or synergistic effects.

Applicant has not provided any objective evidence of criticality, nonobvious or unexpected results that the administration of the particular ingredients' or the manner of

treating lice, combing, shampooing, rinsing, or ingredient concentrations provides any greater or different level of prior art expectation as claimed, and the use of ingredient for the functionality for which they are known to be used is not basis for patentability

### ***Response to Arguments***

Applicant's arguments filed 8/05/2010 have been fully considered but they are not persuasive. Applicant still argues that only IPM kills now; but in fact SINGER shows only IPM kills. IT'S NOT the preferred or synergistic formulation, but it meets the instant claims. The argument as to only 15 % kill is not sustainable, as applicant does not require any kill at all.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to NEIL LEVY whose telephone number is 571-272-0619. The examiner can normally be reached on Tuesday-Friday, 7 AM to 5:30 PM EST..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, ROBERT A. WAX can be reached on 571-272-0623. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/NEIL LEVY/  
Primary Examiner, Art Unit 1615 8/26/2010